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EXAMINER	
KOSSON, ROSANNE	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Applicant's arguments filed on September 22, 2008 have been considered, but they are largely a repeat of previous arguments and are not persuasive for reasons that have been discussed in the previous Office actions. Regarding Applicant's Declaration under 37 CFR §1.131, this Declaration has not been and cannot be rejected; only claims can be rejected. All of Applicant's documents have been considered. But, as previously discussed, the evidence submitted with the Declaration does not show reduction to practice of the subject matter of the instant claims before the priority date of Erwin. Applicant's documents show that he was given the assignment of producing a solution of co Q10 (coenzyme Q10) in d-limonene on March 13, 2003 and that on March 14-19, 2003, Applicant prepared several such solutions. Applicant's position in his responses of July 12, 2007, August 31, 2006, April 28, 2006 and December 20, 2005 is that preparing a soft gel containing a solution of co Q10 in d-limonene is not an obvious modification of making that solution. Thus, in view of the prosecution history, Applicant cannot now assert that the solution is the same thing as the soft gel containing the solution. Further, if making the soft gel preparation is not an obvious modification, the intent to make the soft gel preparation is not reduction to practice. Presumably, technical difficulties are involved in going from the solution to the soft gel preparation. Moreover, it is not clear or explicit in the e-mail of March 13, 2003 what was to be done with the d-limonene solution with respect to the final formulation of the products in which it was to be used. As for the sentence on the notebook page stating that adding pure limonene to a soft gel capsule is not really practical although Soft Gel, Inc. does make such a product, this sentence appears to disclose that a different compound was dissolved in limonene and that then that solution was encapsulated in soft gels as a commercial product. On this date, March 14, Applicant was working out limonene-oil formulations for co Q10. The product was not yet finished.

Regarding Erwin, Applicant asserts that the application is not enabled because Erwin uses a temperature of 42 °C, while Applicant uses room temperature to prepare the limonene solution of co Q10. But, the instant claims are not product-by-process claims, the different temperatures do not make different products, and there is no evidence that heating at 42 °C destroys the co Q10, particularly as the instant claims encompass both oxidized and reduced forms. Example 1 on p. 3 of Erwin's provisional application appears to be straightforward for one of skill in the art, such as a chemist or pharmacist. The disclosure does not appear to be hypothetical or prophetic. As for the amount of co Q10 in the d-limonene solution, most of the instant claims do not recite any percentages. Of the claims that do recite percentages, only claims 32 and 42 recite a range for which the lower limit is above 25%. But the term "about" is not defined in the specification, and it cannot be determined what the difference is between 25% and "about 30%." That is, the range of "about 30%" is not specified and may include 25%.

Regarding Weis et al., this reference does disclose a soft gel preparation containing a suspension of 100 mg of co Q10 in 400 mg of soybean oil. But, this is a rather concentrated preparation, 20% by weight of co Q10, which may have exceeded the solubility limit for soybean oil. Weis et al. disclose, however, that the suspension has better bioavailability than the solid dosage form or the emulsions (p. s276). Nevertheless, Weis et al. are not the most relevant prior art, as the claims are drawn to a soft gel comprising a solution of co Q10 in limonene. As previously discussed, Folkers et al. disclose an aqueous emulsion of co Q10 in soybean oil, a soft gel containing co Q10 dissolved in soybean oil and that co Q10 is soluble in various vegetable oils, such as soybean oil (see col. 4, lines 33-46, and col. 6, lines 16-29).

Regarding Soft Gel (the EP reference), as discussed in all of the previous Office actions, Soft Gel discloses a soft gel containing a solution of co Q10 in rice bran oil and vitamin E. Applicant has, at times, taken the position that the content of the soft gel is a suspension, not a

solution. But, Soft Gel was never used in an anticipation rejection, and the obviousness rejection is that it would have been obvious to one of ordinary skill in the art at the time of the invention to replace the rice bran oil of Soft Gel with limonene, because Erwin and Garti et al. disclose that co Q10 is soluble in d-limonene.

Davidson et al. have also been discussed in all of the previous Office actions. To reiterate, the claims do not require that the co Q10 be dissolved in the fish oil. The claims recite simply that the composition further comprises the carrier fish oil. But, fish oil was a known nutraceutical at the time of the invention (for reducing atherogenic blood lipids). Also, because co Q10 is a lipophilic compound that is soluble in plant oils, one of ordinary skill in the art at the time of the invention would have expected co Q10 to be soluble in an animal oil.

Regarding an In re: Kerkhoven rejection, there is no In re: Kerkhoven rejection in this case. This type of rejection was made in a copending case, Application No. 10/953328. But, the instant claims are broader with respect to the co Q10 solution and recite a solution of co Q10 in limonene. Certain dependent claims recite that the composition further comprises a carrier that may be soybean oil, but these claims do not recite that the co Q10 is soluble in the carrier. Earlier versions of the copending claims recited a solution of co Q10 in a mixture of limonene and a carrier.

The instant rejection is not a hindsight rejection, as it is based on the prior art, and the motivation to combine the references comes from the prior art. As for a long-felt need in the art and a solution containing more than 5% co Q10, as noted by Applicant, co Q10 has been formulated in many different ways to improve its bioavailability (delivery to cells). Thus, many scientists have addressed this problem. The specification, however, does not disclose comparative results for the bioavailability of co Q10 for the claimed product vs. other commercial products or other products disclosed in the literature. Only claims 32, 33, 42 and 43

recite a composition in which the concentration of co Q10 is above 5%, and Erwin discloses 25%. Thus, in view of the teachings of the prior art, the claimed invention is still considered to be an obvious modification of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is (571)272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Rosanne Kosson
Examiner, Art Unit 1652

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